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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/987,372      | 12/09/97    | VENKATRAMAN          | S ARC-2630          |

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HM42/1019

| EXAMINER  |              |
|-----------|--------------|
| WEBMAN, E |              |
| ART UNIT  | PAPER NUMBER |
| 1615      |              |

DATE MAILED: 10/19/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

|                                     |                                    |
|-------------------------------------|------------------------------------|
| Application No.<br><b>08/947372</b> | Applicant(s)<br><b>VENKATRAMAN</b> |
| Examiner<br><b>WEBMAN</b>           | Group Art Unit<br><b>1615</b>      |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on 12/9/97.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-38 is/are pending in the application.
- Of the above claim(s) 1-21, 31-38 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 22-30 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☒ Notice of References Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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Restriction to one of the following inventions is required under  
35 U.S.C. 121:

- I. Claims 1-10, drawn to a intermediate composition, classified in  
class 424, subclass 486.
- II. Claims 11-21, drawn to a composition, classified in class 604,  
subclass 304.
- III. Claims 22-30, drawn to a method of use, classified in class 514,  
subclass 944.
- IV. Claims 31-38, drawn to method of making, classified in class 523,  
subclass 300+.

The inventions are distinct, each from the other because:

Inventions I and II are related as mutually exclusive species in an  
intermediate-final product relationship. Distinctness is proven for claims in this  
relationship if the intermediate product is useful to make other than the final  
product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably  
distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is

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deemed to be useful as an intermediate for a cross-linked gel and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions IV and I, II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as using a higher concentration of polymer without freeze thawing or drying.

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Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as the addition of other moisture <sup>+</sup>regaining compounds.

Should applicants elect Group II, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: Gel, Transdermal, Electrotransport, Capsule, Ointment, Cream, Spray, Suppository.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Drug Delivery Vehicles are generic.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Should applicant elect Group IV, the following election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: A method of making using freeze thawing and the method using drying.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, method<sup>s</sup><sub>1</sub> of making are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with D. B. Miller on 8/26/98 a provisional election was made with traverse to prosecute the invention of Group III, claims 22-30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-21, 31-38 are withdrawn from further



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consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The upper limit of Y in claims 26-27.

Claims 22-30 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for viscosities of 10,000 to 400,000 and a concentration of 10-30% with the degree of hydrolysis from 95-99..% or the concentration is greater than that determined by the <sup>formulae</sup> ~~following~~ disclosed, does not reasonably provide enablement for polymers of <sup>any</sup> ~~my~~ viscosity and <sup>any</sup> ~~my~~ relationship of concentration to degree of hydrolysis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

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Claims 22-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "In a manner is vague", rendering the claim language circular.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-30 rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al.

Kobayashi et al disclose that a 20% freezing thawed solution of polyvinyl alcohol of degree of polymerization of 1000 and a degree of hydrolysis of 98% demonstrated 0.770% water removal due to syneresis (example 5 column 10).

No claim allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 08-4432. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

WEBMAN:tcj  
October 5, 1998



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500